

CAUSE NO. \_\_\_\_\_

IN THE MATTER OF

§ IN THE DISTRICT COURT OF

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WOMB WITH A VIEW, LLC

§ \_\_\_\_\_ JUDICIAL DISTRICT

### **ASSURANCE OF VOLUNTARY COMPLIANCE**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State”) and comes WOMB WITH A VIEW, LLC, (“Respondent”) and respectfully submit the following Assurance of Voluntary Compliance (“AVC”) in accordance with the Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.58, (“DTPA”).

1. Respondent WOMB WITH A VIEW, LLC, a Delaware corporation, had an office located at 5616 S. W. Green Oaks Blvd, Suite E, Arlington, Texas 76107 and its home office is located at 1040 S. Cedar Crest Blvd, Allentown, PA 18103.

2. The Texas Department of Health (“TDH”), now re-organized as the Texas Department of State Health Services, conducted an inspection on April 13, 2004, and found that Respondent was conducting fetal ultrasound imaging procedures using a prescription ultrasound device without the supervision of a practitioner licensed by Texas law to use such devices and without a prescription or other order from a practitioner for each ultrasound performed in

violation of state and federal medical device laws and regulations. In addition, TDH found that Respondent promoted ultrasound imaging procedures for keepsake purposes or emotional and maternal well-being which are uses not approved by the Federal Food and Drug Administration (“FDA”). Respondent’s website promoted the use of diagnostic ultrasound systems as “state of the art 3D technology” for a “30-minute video” with “gender verification, an estimate of the fetal heartrate, and an amazing educational experience.” TDH also determined that Respondent did not have written Medical Device Reporting (“MDR”) procedures for review as required by federal and state regulations.

3. The State alleges and Respondent deny that Respondent has violated the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.001, *et seq.* and the Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.41, *et seq.*

4. The State and Respondent have agreed to settle fully these differences and have agreed to do so by entering into the AVC; therefore Respondent admits to the applicability of the DTPA for jurisdictional purposes of entering into the AVC.

5. As used in this AVC, the following terms shall have the following meaning:

- A. “Advertising” means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.
- B. “Adulterate” a device means to use a device in violation of § 431.111 of the Texas Health and Safety Code, including but not limited to, using a diagnostic ultrasound system for a use not approved by FDA or using a diagnostic ultrasound system for keepsake purposes or emotional and maternal well-being.

- C. “Diagnostic ultrasound systems”, as used in this section, shall mean any diagnostic ultrasound system, ultrasonic pulsed doppler imaging system, or ultrasound transducer, as defined in 21 CFR § 892.1550, 21 CFR § 892.1560, and 21 CFR § 892.1570.
- D. “Dangerous drug” means a device or drug that is unsafe for self-medication that bears or is required to bear a federal legend such as: Caution: federal law prohibits dispensing without prescription as defined by Section 483, Dangerous Drug Act, of the Health and Safety Code.
- E. “False advertising” of a food, drug, device, or cosmetic means advertising that is false, deceptive, or misleading in any particular.
- F. “FDA” means the Federal Food and Drug Administration.
- G. “Federal Act” means the Federal Food, Drug and Cosmetic Act.
- H. “Labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
- I. “Medical device reporting requirements” means reporting requirements in 21 CFR § 803.
- J. “Misbrand” a device means any violation of §431.112 of the Texas Health and Safety Code, including but not limited to, labeling for a device if it is false or misleading in any particular; labeling of a device without adequate directions for use; advertising of a restricted device if the advertising is false or misleading in any particular; or if a restricted device is sold, distributed, or used in violation of federal regulations.
- K. “Physician” means a person licensed to practice medicine in this state as defined in § 151.002 (a)(12) of the TEXAS OCCUPATIONS CODE ANN.
- L. “Practitioner” means a person as defined in §483.001 (12), Texas Dangerous Drug Act, TEX. HEALTH AND SAFETY CODE ANN.
- M. “Prescription device(s)” means device(s) which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared; and therefore are required to bear a federal legend that states:

“Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_” with the blank filled in with the designation of a practitioner licensed by the law of the State in which he practices to use or order the use of the device, as required by 21 CFR § 801.109.

### **PROHIBITED PRACTICES**

6. In response to these allegations and without Respondent admitting the truth of these allegations and specifically denying same, Respondent agrees and voluntarily assures the State that from the date of the signing of this AVC, which shall be filed with the appropriate Court, that Respondent and each and all of their directors, officers, agents, affiliates, employees, successors and assigns, and all persons or entities in active concert or participation with Respondent and who have received actual notice of this AVC, by personal service or otherwise, shall not make the following representations, do the following acts, or engage in the following practices in the pursuit and conduct of trade or commerce within the State of Texas, as set forth below:

- A. Purchase and possess prescription diagnostic ultrasound systems without a practitioner licensed under Texas law to purchase and possess such devices;
- B. Use prescription diagnostic ultrasound systems without the supervision of a practitioner licensed by Texas law to use such devices;
- C. Use prescription diagnostic ultrasound systems without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;

- D. Use prescription diagnostic ultrasound systems for keepsake purposes or emotional and maternal well-being for which FDA has not approved these devices;
- E. Falsely advertise or falsely represent that prescription diagnostic ultrasound systems can be used for keepsake purposes or emotional and maternal well-being if FDA has not approved these devices for such uses;
- F. Fail to disclose that Respondent's prescription diagnostic ultrasound system is approved only for diagnostic ultrasound;
- G. Fail to comply with federal medical device reporting requirements, as required by 21 CFR § 803;
- H. Fail to disclose that prescription diagnostic ultrasound systems are only to be used under the written order and supervision of a practitioner licensed in Texas;
- I. Misbrand or adulterate prescription diagnostic ultrasound systems in commerce;
- J. Cause confusion as to the approval of a good by allowing consumers to purchase the use of prescription diagnostic ultrasound systems for keepsake purposes or emotional and maternal well-being; and
- K. Fail to provide written notice to any agent, servant, employee, affiliate or representative at any of Respondent's locations of the existence and terms of these prohibited acts, and of their duty to comply with the terms set forth herein.

7. Respondent has read and understand this AVC and enter into it voluntarily, having been advised by its undersigned legal counsel of the meaning and effect of each provision of this AVC.

8. Respondents further agrees that the State's execution of this AVC does not constitute an approval by the State of Texas of any its practices and are not to make any representations to the contrary.

9. As set forth in TEX. BUS. & COM. CODE §17.58(c), notwithstanding any other provision of this AVC, Respondent acknowledges that unless this AVC has been rescinded by agreement of the parties, or voided by the Court for good cause, subsequent failure to comply with the terms of this AVC, is prima facie evidence of a violation of the DTPA and shall give rise to a right of action by the STATE OF TEXAS under the provisions of the Texas, Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN., §431.001, *et seq.* and the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41, *et seq.*

10. It is also agreed and understood that this AVC does not affect individual rights of action.

11. The acceptance of this AVC is conditioned upon payment by Respondent to the State of the sum of Five Thousand Dollars (\$5,000.00) as attorneys fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE § 402.006(c).

12. The acceptance of this AVC is conditioned upon payment by Respondent to the State of the sum of Two Thousand Five Hundred Dollars (\$2,500.00) to the Texas Department of State Health Services, formerly the Texas Department of Health, to cover their investigative costs pursuant to § 431.047 of the TFDCA.

13. The State agrees, by its execution of this AVC, that if Respondent fully complies with the terms of the AVC that the State will not make any further claims or take any other

enforcement action against Respondent with regard to the factual allegations contained in this AVC that occurred prior to the signing of this AVC.

14. All costs of court are adjudged against Respondent.

Signed this \_\_\_\_ day of \_\_\_\_\_, 2004.

Date: \_\_\_\_\_

**Respondent WOMB WITH A VIEW, LLC**

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DONALD V. FAIRHURST  
Chief Executive Officer

Attorney for Womb With A View, LLC.

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